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A Double-blind Randomized Controlled Trial for the Effects of Dry Needling on Upper Limb Dysfunction in Patients with Stroke

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ABSTRACT: Spasticity is one of the main complications of a stroke. This double-blind, randomized controlled trial aimed to compare the result of three sessions of dry needling (DN) versus sham DN on the affected upper limbs in post-stroke survivors. We recruited 24 patients (age 57.0 ± 9.6 years; male 71%). Patients were randomly allocated to two groups: a DN group and a sham DN group. The primary outcome measures were the Modified Modified Ashworth Scale (MMAS) and the Box and Block Test (BBT). Secondary outcome measures included active and passive wrist range of motion (AROM and PROM). All assessments were measured at baseline, immediately after the last session of the intervention, and one month later. Patients in the DN group had improved upper limb spasticity and passive wrist range of motion compared to control group (P<0.05). There were no between-group differences in other outcome measures (P>0.05). Dry needling is a useful method for improving muscle spasticity in the upper limbs of patients with stroke.

Keywords: Stroke; Spasticity; Dry needling; Sham dry needling

INTRODUCTION

Stroke is the second most common cause of death (Lozano et al., 2012) and one of the three leading causes of disability-adjusted life-years (DALYs) across the world (Murray et al., 2013). Despite the reduction in mortality rates for stroke over the past two decades, the global disease burden rate has increased (Feigin et al., 2014). In Iran, , there is a higher stroke incidence than in Western countries (Feigin et al., 2014; Azarpazhooh et al., 2010).

If not controlled, spasticity can result in MUSCLE contracture leading to mobility impairments (Ghaffari et al., 2019). Spasticity contributes to functional disability, ADL dependency, and a diminished quality of life (Sc et al., 2018; Duncan et al., 2003). Hence, the treatment of spasticity may restore active, voluntary movements and regain selective motor function, reduce the level of disability, and improve individual health levels (Zorowitz, Gillard, & Brainin, 2013). Post-stroke spasticity affects the flexors of the upper limb, leading to upper limb hemiplegic posture and hand dysfunction (Opheim, Danielsson, Murphy, Persson, & Sunnerhagen, 2014).

Dry needling (DN) has emerged as a relatively safe and cost-effective procedure for treating muscle spasticity (Shariat et al., 2018; Ghannadi et al., 2020). Due to the relatively high costs associated with post-stroke care (Lim et al., 2015), finding a low cost and effective method for improving post-stroke spasticity is essential. Thus, we aimed to determine the effects of DN on post-stroke spasticity. We hypothesized that post-stroke survivors receiving three sessions DN

would gain significant improvements in upper limb spasticity, passive range of motion, and patients' function after stroke compared to control.

MATERIALS AND METHODS

Design

The study was a double-blind, randomized controlled trial. The review board of the Sports and Exercise Medicine Research Center and the Ethical Committee of Tehran University of Medical Sciences approved the study protocol. All patients signed an informed consent form before the study initiation.

Participants

The trial was conducted between August and October 2018 in the Sports Medicine Research Center, Tehran University of Medical Sciences, Iran.

The inclusion criteria were: 1) age between 18≥; 2) at least six months since the stroke; 3) the first-ever stroke resulted in hemiplegia; 4) wrist flexor Modified Modified Ashworth Scale (MMAS) score ≥1; 5) not taking any medications for spasticity, and 6) able to understand and follow instructions. The exclusion criteria were: 1) having any contraindication to dry needling; 2) history of neurological pain; 3) fixed muscle contracture of the affected wrist; 4) currently receiving other treatment protocols, and 5) unwillingness to participate in the study.

Outcome measurements

The primary outcome measures were the MMAS, and the Box and Block Test (BBT). Secondary outcome measures were active and passive wrist range of motion (AROM and PROM) measured at baseline (T0), immediately after the end of treatment (T1), and at one-month follow-up (T2).

Procedures

Baseline clinical characteristics, including age, sex, body mass index (BMI), time since stroke, hemiplegic side, co-morbidities, and medication usage were recorded. Dry needling was delivered for three sessions, separated by a 48-hours interval between sessions. An experienced physiotherapist, blinded to the patient allocation, preformed the assessments.

Modified Modified Ashworth Scale

The MMAS is a valid and reliable tool for assessing post-stroke spasticity, using a 0 to 4 scale. A recent study concluded that MMAS is an appropriate scale for clinical practice and research (Banky, Ryan, Clark, Olver, & Williams, 2017). The Persian version of the MMAS was used, which has been validated previously in post-stroke survivors (Nakhostin Ansari et al., 2012).

Range of motion

Active and passive wrist extension was measured in the sitting position using a standard manual goniometer.

Box and block test

Hand dexterity was assessed with the BBT. With this test, a box is divided into two opposing equal compartments. Patients were instructed to move 150 standard blocks from one compartment into the other compartment one block at a time using their affected hand. The assessor encouraged patients to perform the test as quickly as possible (Fakhari et al., 2017).

Dry needling procedure

Dry needling was performed with the patient in the supine position, the affected arm alongside the trunk, the shoulder at 45° abduction, the elbow was extended, and the forearm in supination. Disposable sterile stainless-steel needles (size: 0.25 mm x 25 mm; SMC, Seoul, Korea) were used with the fast-in and fast-out cone shape technique. Target muscles were the flexor carpi radialis (FCR) and flexor carpi ulnaris (FCU). The FCR was needled in the medial forearm 4 cm below and 1 cm medially from the midpoint of the elbow crease (Figure 1A and 1B). The FCU was needled at the midpoint of the proximal third segment of a line connecting the medial epicondyle to the ulnar styloid process (Figure 1C). Each muscle was needled for 1 minute. An experienced sports medicine specialist not involved in the assessment of the patients completed the treatments. In the control group, the same protocol was carried out using a sham needle (Figure 2). All patients were instructed not to have any other treatments during the study and follow up period, including other physical therapy treatments, medications, acupuncture, or dry needling.

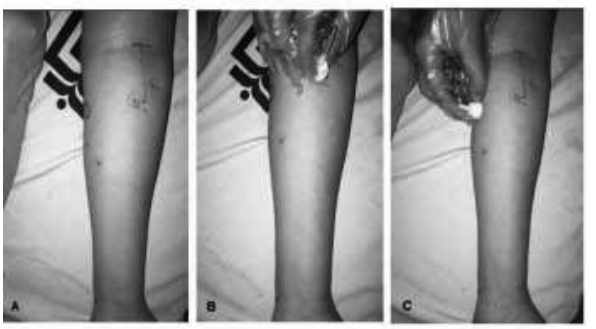

Figure 1. Location of dry needling (A). Dry needling was applied to the flexor carpi radials muscles (B) and the flexor carpi ulnaris muscles (C).

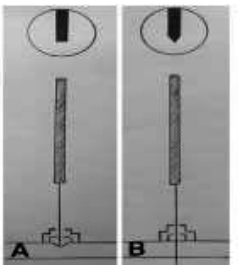

Figure 2. Real (A) and sham (B) needle.

Randomization and blinding

Patients were allocated to two groups by computer-generated randomization in blocks of 24 in a 1:1 ratio. The patients were randomized to 1 of 2 groups: a DN group and a sham DN group. A research assistant not involved in the study opened the sealed opaque envelopes and assigned the patients to their respective groups. The patients and assessor were blinded to the treatment allocation.

Sample size estimates

The estimated sample size for each group was calculated 11 (alpha=0.05; Beta 0.8) using data provided by Fakhari et al. (2017). With an anticipated attrition rate of 10%, the number of patients in each group was increased to 12.

Statistical Analyses

The SPSS for Windows v20 (IBM, NY, USA) was used for all statistical analyses. Data normality was checked by the Kolmogorov-Smirnov test. Baseline characteristics between groups were compared using an independent t-test and Mann-Whitney U test. Differences over time between the groups were assessed by a 2×3 (group by time) repeated measures analysis of variance. Bonferroni post hoc adjustments were carried out where necessary with a partial eta (η_p^2). Partial eta^2 effect sizes were interpreted as 0.25, 0.40, and >0.40 representing small medium, and large effect sizes (Richardson, 2011). The kruskal-wallis was used for between group comparison and Friedman's test was considered to test for the effects of interventions on spasticity assessed by an ordinal MMAS. A post hoc Wilcoxon Signed-Rank Test (WSRT) was applied for paired differences between the testing time points within groups. *P*-values less than 0.05 were considered significant.

RESULTS

We recruited 24 patients (age 57.0 ± 9.6 years; BMI 26.4 ±1.8; male/female:17/7 for the study. There were no significant difference in patients' characteristics between-groups (P>0.05).

Modified Modified Ashworth Scale

There was a significant differences of MMAS scores in the DN group (X^2(2) =15.2, p<.001). There was not statistically difference in time points in control group (X^2(2) =2.00, p=0.37). A kruskal-wallis test showed that there was a statistically significant difference between two groups in post-test (P=0.012).

Table-3 The Modified Modified Ashworth Scale (MMAS). Scores in both groups presented as the median.

	Intervention Group (n=12)			Control Group (n=12)		
MMAS	Pre-test	Post-test	Follow-up	Pre-test	Post-test	Follow-up
0	0	5 (41.7%)	1 (8.3%)	0	0	0
1	6 (50%)	3 (25%)	7 (58.3%)	3 (25%)	4 (33.3%)	4 (33.3%)
2	3 (25%)	4 (33.3)	2 (16.7%)	5 (41.7%)	4 (33.3%)	4 (33.3%)
3	3 (25%)	0	2 (16.7%)	4 (33.3%)	4 (33.3%)	4 (33.3%)
4	0	0	0	0	0	0

BBT

The group-by-time interaction (P=0.187, F $_{(2, 44)}$ =1.742, η_p^2=.073) for BBT was not significant. A time effect (p=.421, F $_{(2, 44)}$ =.883, η_p^2=.039) was also not evident. Between groups compression showed no significant changes (P>0.05).

PROM for wrist movement

A significant group-by time interaction (P<0.001, F $_{(2, 44)}$ =72.315, η_p^2=.767) showed that the two groups responded differently to the intervention. A significant time effect (P<0.001, F $_{(2, 44)}$ =69.234, η_p^2=.759) also occurred (Table 1).. Between group compression showed significant differences (P>0.05).

AROM for wrist movement

The group-by-time interaction (P=0.145, F (1.945, 28.336) =2.193, η_p^2=.011) for AROM was not evident. No significant time effect (p=0.311, F ($_{1.288, 28.336}$) =6.468, η_p^2=.145) was found. Between groups compression showed no significant differences (P>0.05).

Table-1. Changes in wrist extension range of motion and hand dexterity in experimental and control groups (n=24) at baseline (T0), after completion of the intervention (T1), and 4 weeks later (T2).

Variables	Experimental Group (n=12)			Control Group (n=12)			Time Effect (*P*-value)	Between group (*P*-value)	Group by Time Interaction (*P*-value)
	Pre test(T0)	Post test(T1)	Follow-up(T2)	Pre test(T0)	Post test(T1)	Follow-up(T2)			
PROM (degrees)	47.75±19.09	93.25±3.98	94.08±4.09	63.58±22.03	64.08±22.23	64.18±20.98	#	0.040	#
AROM (degrees)	23.83±27.88	26.16±27.59	25.83±27.59	14.00±15.77	14.50±16.12	14.75±16.12	0.311	0.249	0.145
BBT	6.34±9.28	7.00±9.42	6.84+9.54	3.41±3.05	3.34±2.74	3.25±2.77	0.421	0.244	0.187

Note: Mean ± SD for outcome measurements. AROM: Active Range of Motion; PROM: Passive Range of Motion; BBT: Box and Block Test. #*P*<.001

DISCUSSION

Our study examined the effects of three sessions of dry needling vs. sham needling on spasticity of post-stroke survivors. We found improvements in upper limb spasticity (MMAS) and wrist PROM compared to control. The improvements remained in wrist passive range of motion one month later.

A decrease in muscle spasticity is similar to findings from other studies with stroke (Ansari, Naghdi, Fakhari, Radinmehr, & Hasson, 2015; Salom-Moreno et al., 2014). The possible mechanisms are still unclear. Central modulation may lead to changes in the spinal reflex's excitability with activation of the noxious inhibitory control system. Furthermore, biomechanical changes in the needled muscles could consider as another reason (Ansari et al., 2015; Fakhari et al., 2017; Gallego & del Moral, 2007). Increased wrist PROM could be due to the localized biomechanical changes in contractile elements in agreement with previous studies (Ansari et al., 2015; Fakhari et al., 2017; Gallego & del Moral, 2007).

Spasticity is considered one of the most significant factors that interfere with motor recovery (Van Kuijk, Geurts, Bevaart, & Van Limbeek, 2002). Improvements in spasticity may lead to functional recovery (Francis et al., 2004). Fakhari et al. showed a negative association between spasticity and increased AROM following one session of DN (Fakhari et al., 2017). The authors proposed that repeated task-oriented exercises combined with DN treatments may lead to better improvements in hand function (Fakhari et al., 2017). We did not find any evidence of increased AROM. However, functional impairment in the post-stroke upper limbs may be due to a neural drive down-regulation to skeletal muscles, and reduced connectivity to the corticospinal system (Bowden, Taylor, & McNulty, 2014). Sanchez-Mila et al. showed no improvement in motor function after one session of DN in the lower extremity; moreover, they reported increased passive range of motion and decreased spasticity (Sánchez-Mila et al., 2018). Fakhari reported a significant positive relation between BBT and AROM, leading the authors to conclude that wrist AROM is an important factor for improving hand function in post-stroke survivors (Fakhari et al., 2017). In our study, BBT showed no improvement, which is understandable since we did not observe any increase in AROM following three sessions of DN.

STUDY LIMITATION

The study is not without limitations. Our intervention included three sessions of DN, and it is conceivable that additional treatment sessions could lead to more significant and longer-lasting results. Hence, further studies with additional sessions are required. Combining DN with other therapies, e.g., exercises, warrant further investigations to determine if combined treatments improve outcomes. Finally, participants were not follow-up for long term.

CONCLUSION

Three dry needling sessions appear to be a useful method for improving muscle passive range of motion in the upper limb in patients following stroke.

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Ethical Approval: Tehran University approved this study of Medical Sciences (IR.TUMS.VCR.REC.1397.721).

Declaration of Conflicting Interests: The authors declared no potential conflicts of interest concerning the research, authorship, and publication of this article.

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